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TITLE: ACTIVATED CHARCOAL BASED COMPOSITION AND METHOD FOR REDUCING HANGOVER SYMPTOMS ASSOCIATED WITH THE CONSUMPTION OF ALCOHOL CONTAINING BEVERAGES

PUBN-DATE: July 18, 2002

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## ABSTRACT:

CHG DATE=20020802 STATUS=O>The invention provides a composition which is effective in the prevention or delay of the onset of 'side effects associated with alcohol consumption or the reduction or alleviation of those effects. The composition of the invention includes activated charcoal and limestone, optionally activated limestone. Optionally, the composition of the invention also includes vitamin B1 and/or other agents such as fatigue relieving agents. Preferably, the composition of the invention is provided in the form of tablets or powder encapsulated in a gelatin capsule. The composition of the invention is provided in pre-dosed quantities varying from between about 100 and 500 milligrams per dose. The invention also provides a method of reducing or alleviating the deleterious effects associated with alcohol consumption. The method includes administration, preferably multiple administration at regularly spaced intervals before, during, and after alcohol consumption of a composition containing activated charcoal and activated limestone.

### 2133.03 [R-1] Rejections Based on "Public Use" or "On Sale"

35 U.S.C. 102(b) "contains several distinct bars to patentability, each of which relates to activity or disclosure more than one year prior to the date of the application. Two of these - the public use' and the on sale' objections - are sometimes considered together although it is quite clear that either may apply when the other does not." *Dart Indus. v. E.I. du Pont de Nemours & Co.*, 489 F.2d 1359, 1365, 179 USPQ 392, 396 (7th Cir. 1973). There may be a public use of an invention absent any sales activity. Likewise, there may be a nonpublic, e.g., "secret," sale or offer to sell an invention which nevertheless constitutes a statutory bar. *Hobbs v. United States*, 451 F.2d 849, 859-60, 171 USPQ 713, 720 (5th Cir. 1971).

In similar fashion, not all "public use" and "on sale" activities will necessarily occasion the

identical result. Although both activities affect how an inventor may use an invention prior

to the filing of a patent application, "non-commercial" 35 U.S.C. 102(b) activity may not be viewed the same as similar "commercial" activity. See MPEP § 2133.03(a) and § 2133.03(e)(1). Likewise, "public use" activity by an applicant may not be considered in the same light as similar "public use" activity by one other than an applicant. See MPEP § 2133.03(a) and § 2133.03(e)(7). Additionally, the concepts of "completion" and "experimental use" have differing significance in "commercial" and "non-commercial" environments. See MPEP § 2133.03(c) and § 2133.03(e) - § 2133.03(e)(6).

It should be noted that 35 U.S.C. 102(b) may create a bar to patentability either alone, if the device in public use or placed on sale anticipates a later claimed invention, or in conjunction with 35 U.S.C. 103, if the claimed invention would have been obvious from the device in conjunction with the prior art. *LaBounty Mfg. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1071, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992).

#### POLICY CONSIDERATIONS

(A) "One policy underlying the [on-sale] bar is to obtain widespread disclosure of new inventions to the public via patents as soon as possible." *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989).

(B) \* > Another policy underlying the < public use and on-sale bars \*\* > is < to prevent the inventor from commercially exploiting the exclusivity of his [or her] invention substantially beyond the statutorily authorized period. *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989). See MPEP § 2133.03(e)(1).

(C) Another underlying policy for the public use and on-sale bars is to discourage "the removal of inventions from the public domain which the public justifiably comes to believe are freely available." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 USPQ2d 1587, 1591 (Fed. Cir. 1990).

#### 2133.03(a) "Public Use"

#### ONE USE IN THE PUBLIC DOMAIN BY ONE PERSON MAY BAR A PATENT

"[T]o constitute the public use of an invention it is not necessary that more than one of the

patent articles should be publicly used. The use of a great number may tend to strengthen

the proof, but one well defined case of such use is just as effectual to annul the patent as many.” Likewise, it is not necessary that more than one person use the invention. *Egbert v.*

*Lippmann*, 104 U.S. 333, 336 (1881).

#### **PUBLIC KNOWLEDGE IS NOT NECESSARILY PUBLIC USE UNDER 35 U.S.C. 102(b)**

Mere knowledge of the invention by the public does not warrant rejection under 35 U.S.C. 102(b). 35 U.S.C. 102(b) bars public use or sale, not public knowledge. *TP Labs., Inc., v. Professional Positioners, Inc.*, 724 F.2d 965, 970, 220 USPQ 577, 581 (Fed. Cir. 1984).

Note, however, that public knowledge may provide grounds for rejection under 35 U.S.C. 102(a). See MPEP § 2132.

#### **A. Commercial Versus Noncommercial Use and the Impact of Secrecy**

##### **1. “Public Use” and “Non-secret Use” Are Not Necessarily Synonymous**

“Public” is not necessarily synonymous with “non- secret.” The fact “that non-secret uses of the device were made [by the inventor or someone connected with the inventor] prior to

the critical date is not itself dispositive of the issue of whether activity barring a patent under 35 U.S.C. 102(b) occurred. The fact that the device was not hidden from view may make the use not secret, but nonsecret use is not ipso facto public use’ activity. Nor, it must be added, is all secret use ipso facto not public use’ within the meaning of the statute,” if the inventor is making commercial use of the invention under circumstances

which preserve its secrecy. *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 972, 220 USPQ 577, 583 (Fed. Cir. 1983) (citations omitted).

##### **2. Even If the Invention Is Hidden, Inventor Who Puts Machine or Article Embodying the Invention in Public View Is Barred from Obtaining a Patent as the Invention Is in Public Use**

When the inventor or someone connected to the inventor puts the invention on display or sells it, there is a “public use” within the meaning of 35 U.S.C. 102(b) even though by its very nature an invention is completely hidden from view as part of a larger machine or article, if the invention is otherwise used in its natural and intended way and the larger machine or article is accessible to the public. In *re Blaisdell*, 242 F.2d 779, 783, 113 USPQ 289, 292 (CCPA 1957); *Hall v. Macneale*, 107 U.S. 90, 96-97 (1882); *Ex parte Kuklo*, 25 USPQ2d 1387, 1390 (Bd. Pat. App. & Inter. 1992) (Display of equipment including the structural features of the claimed invention to visitors of laboratory is public use even though public did not see inner workings of device. The person to whom the invention is publicly disclosed need not understand the significance and technical complexities of the invention.).

3. There Is No Public Use If Inventor Restricted Use to Locations Where There Was a Reasonable Expectation of Privacy and the Use Was for His or Her Own Enjoyment  
An inventor’s private use of the invention, for his or her own enjoyment is not a public use. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265, 229 USPQ 805, 809 (Fed. Cir. 1986) (Inventor showed inventive puzzle to close friends while in his dorm room and later the president of the company at which he was working saw the puzzle on the inventor’s desk and they discussed it. Court held that the inventor retained control

and thus these actions did not result in a "public use.").

#### B. Use by Third Parties Deriving the Invention from Applicant

##### An Invention Is in Public Use If the Inventor Allows Another To Use the Invention Without Restriction or Obligation of Secrecy

"Public use" of a claimed invention under 35 U.S.C. 102(b) occurs when the inventor allows another person to use the invention without limitation, restriction or obligation of secrecy to the inventor." In re Smith, 714 F.2d 1127, 1134, 218 USPQ 976, 983 (Fed. Cir. 1983). The presence or absence of a confidentiality agreement is not itself determinative of the public use issue, but is one factor to be considered along with the time, place, and circumstances of the use which show the amount of control the inventor retained over the invention. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265, 229 USPQ 805, 809 (Fed. Cir. 1986). See *Ex parte C*, 27 USPQ2d 1492, 1499 (Bd. Pat. App. & Inter. 1992) (Inventor sold inventive soybean seeds to growers who contracted and were paid to plant the seeds to increase stock for later sale. The commercial nature of the use of the seed coupled with the "on-sale" aspects of the contract and apparent lack of confidentiality requirements rose to the level of a "public use" bar.); *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (Public use found where inventor allowed another to use inventive corset insert, though hidden from view during use, because he did not impose an obligation of secrecy or restrictions on its use.).

#### C. Use by Independent Third Parties

##### Use by an Independent Third Party Is Public Use If It Sufficiently "Informs" the Public of

##### the Invention or a Competitor Could Reasonably Ascertain the Invention

Any "nonsecret" use of an invention by someone unconnected to the inventor, such as someone who has independently made the invention, in the ordinary course of a business for trade or profit may be a "public use," *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 374-76, 197 USPQ 134, 138-40 (5th Cir. 1978).

Additionally, even a "secret" use by another inventor of a machine or process to make a product is "public" if the details of the machine or process are ascertainable by inspection or analysis of the product that is sold or publicly displayed. *Gillman v. Stern*, 114 F.2d 28, 46 USPQ 430 (2d Cir. 1940); *Dunlop Holdings, Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 36-7, 188 USPQ 481, 483-484 (7th Cir. 1975). If the details of an inventive process are not ascertainable from the product sold or displayed and the third party has kept the invention as a trade secret then that use is not a public use and will not bar a patent issuing to someone unconnected to the user. *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 310 (Fed. Cir. 1983). However, a device qualifies as prior art if it places the claimed features in the public's possession before the critical date even if other unclaimed aspects of the device were not publicly available. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1964-65 (Fed. Cir. 1997) (Computer reservation system was prior art even though "essential algorithms of the SABRE software were proprietary and confidential and...those aspects of the system that were readily apparent to the public would not have been sufficient to enable one skilled in

the art to duplicate the [unclaimed aspects of the] system."). The extent that the public becomes "informed" of an invention involved in public use activity by one other than an applicant depends upon the factual circumstances surrounding the activity and how these

comport with the policies underlying the on sale and public use bars. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 USPQ2d 1587, 1591 (Fed. Cir. 1990) (quoting *King Instrument Corp. v. Otari Corp.*, 767 F.2d 833, 860, 226 USPQ 402, 406 (Fed. Cir. 1985)). By way of example, in an allegedly “secret” use by a third party other than an applicant, if a large number of employees of such a party, who are not under a promise of secrecy, are permitted unimpeded access to an invention, with affirmative steps by the party to educate other employees as to the nature of the invention,

the public is “informed.” *Chemithon Corp. v. Proctor & Gamble Co.*, 287 F. Supp. 291, 308, 159 USPQ 139, 154 (D.Md. 1968), *aff’d*, 427 F.2d 893, 165 USPQ 678 (4th Cir. 1970).

Even if public use activity by one other than an applicant is not sufficiently “informing,” there may be adequate grounds upon which to base a rejection under 35 U.S.C. 102(f) and 35 U.S.C. 102(g). See *Dunlop Holdings Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 188 USPQ 481 (7th Cir. 1975). See MPEP § 2137 and § 2138.

2133.03(b) [R-1] “On Sale”

An impermissible sale has occurred if there was a definite sale, or offer to sell, more than 1 year before the effective filing date of the U.S. application and the subject matter of the sale, or offer to sell, fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art. *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1565, 33 USPQ2d 1512, 1514 (Fed. Cir. 1995). >The on-sale bar of 35 U.S.C. 102(b) is triggered if the invention is both (1) the subject of a commercial offer for sale not primarily for experimental purposes and (2) ready for patenting. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67, 48 USPQ2d 1641, 1646-47 (1998). Traditional contract law principles are applied when determining whether a commercial offer for sale has occurred. See *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1048, 61 USPQ2d 1225, 1229 (Fed. Cir. 2001), petition for cert. filed, 71 USLW 3093 (Jul. 03, 2002) (No. 02-39); *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047, 59 USPQ2d 1121, 1126 (Fed. Cir. 2001) (“As a general proposition, we will look to the Uniform Commercial Code (UCC) to define whether ... a communication

or series of communications rises to the level of a commercial offer for sale.”).<

#### I. THE MEANING OF “SALE”

A sale is a contract between parties wherein the seller agrees “to give and to pass rights of property” in return for the buyer’s payment or promise “to pay the seller for the things bought or sold.” *In re Caveney*, 761 F.2d 671, 676, 226 USPQ 1, 4 (Fed. Cir. 1985).

>A contract for the sale of goods requires a concrete offer and acceptance of that offer. See, e.g., *Linear Tech.*, 275 F.3d at 1052-54, 61 USPQ2d at 1233-34 (Court held there was no sale within the meaning of 35 U.S.C. 102(b) where prospective purchaser submitted an order for goods at issue, but received an order acknowledgement reading “will advise-not booked.” Prospective purchaser would understand that order was not accepted.).<

#### A. Conditional Sale May Bar a Patent

An invention may be deemed to be “on sale” even though the sale was conditional. The fact that the sale is conditioned on buyer satisfaction does not, without more, prove that the sale was for an experimental purpose. *Strong v. General Elec. Co.*, 434 F.2d 1042,

1046, 168 USPQ 8, 12 (5th Cir. 1970).

#### B. Nonprofit Sale May Bar a Patent

A "sale" need not be for profit to bar a patent. If the sale was for the commercial exploitation of the invention, it is "on sale" within the meaning of 35 U.S.C. 102(b). In re

Dybel, 524 F.2d 1393, 1401, 187 USPQ 593, 599 (CCPA 1975) ("Although selling the devices for a profit would have demonstrated the purpose of commercial exploitation, the fact that appellant realized no profit from the sales does not demonstrate the contrary.").

#### C. A Single Sale or Offer To Sell May Bar a Patent

Even a single sale or offer to sell the invention may bar patentability under 35 U.S.C. 102(b). Consolidated Fruit-Jar Co. v. Wright, 94 U.S. 92, 94 (1876); Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 836-37, 23 USPQ2d 1481, 1483 (Fed. Cir. 1992).

#### D. A Sale of Rights Is Not a Sale of the Invention and Will Not in Itself Bar a Patent

> The grant of a license to an invention, without more, does not trigger the on-sale bar of 35 U.S.C. 102(b). In re Kollar, 286 F.3d 1326, 1330-32, 62 USPQ2d 1425, 1428-29 (Fed. Cir. 2002).< "An assignment or sale of the rights, such as patent rights, in the invention is not a sale of the invention' within the meaning of section 102(b)." The sale must involve the delivery of the physical invention itself. Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1265, 229 USPQ 805, 809 (Fed. Cir. 1986).

#### E. Buyer Must Be Uncontrolled by the Seller or Offerer

A sale or offer for sale must take place between separate entities. In re Caveney, 761 F.2d 671, 676, 226 USPQ 1, 4 (Fed. Cir. 1985). "Where the parties to the alleged sale are related, whether there is a statutory bar depends on whether the seller so controls the purchaser that the invention remains out of the public's hands. Ferag AG v. Quipp, Inc., 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1515 (Fed. Cir. 1995) (Where the seller is a parent company of the buyer company, but the President of the buyer company had "essentially unfettered" management authority over the operations of the buyer company, the sale was a statutory bar.).

## II. OFFERS FOR SALE

> "Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under §102(b)." Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1048, 59 USPQ2d 1121, 1126 (Fed. Cir. 2001).<

#### A. Rejected or Unreceived Offer for Sale Is Enough To Bar a Patent

Since the statute creates a bar when an invention is placed "on sale," a mere offer to sell is sufficient commercial activity to bar a patent. In re Theis, 610 F.2d 786, 791, 204 USPQ 188, 192 (CCPA 1979). Even a rejected offer may create an on sale bar. UMC Elecs. v. United States, 816 F.2d 647, 653, 2 USPQ2d 1465, 1469 (Fed. Cir. 1987). In fact, the offer need not even be actually received by a prospective purchaser. Wende v. Horine, 225 F. 501 (7th Cir. 1915).

#### B. Delivery of the Offered Item Is Not Required

"It is not necessary that a sale be consummated for the bar to operate." Buildex v. Kason Indus., Inc., 849 F.2d 1461, 1463-64, 7 USPQ2d 1325, 1327-28 (Fed. Cir. 1988) (citations omitted). See also Weatherchem Corp. v. J.L. Clark Inc., 163 F.3d

1326, 1333, 49 USPQ2d 1001, 1006-07 (Fed. Cir. 1998) (A signed purchase agreement prior to the critical date constituted a commercial offer; it was immaterial that there was no delivery of later patented caps and no exchange of money until after critical date.).

C. Seller Need Not Have the Goods "On Hand" when the Offer for Sale Is Made  
Goods need not be "on hand" and transferred at the time of the sale or offer. The date of the offer for sale is the effective date of the "on sale" activity. *J. A. La Porte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1582, 229 USPQ 435, 438 (Fed. Cir. 1986). However, the invention must be complete and "ready for patenting" (see MPEP § 2133.03(c)) before the critical date. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67, 119 S.Ct. 304, 311-12, 48 USPQ2d 1641, 1647 (1998). See also *Micro Chemical, Inc. v. Great Plains Chemical Co.*, 103 F.3d 1538, 1545, 41 USPQ2d 1238, 1243 (Fed. Cir. 1997) (The on-sale bar was not triggered by an offer to sell because the inventor "was not close to completion of the invention at the time of the alleged offer and had not demonstrated a high likelihood that the invention would work for its intended purpose upon completion."); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985) (Where there was no evidence that the samples shown to the potential customers were made by the new process and apparatus, the offer to sell did not rise to the level of an on sale bar.). Compare *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 221 USPQ 561 (Fed. Cir. 1984) (Where a "make shift" model of the inventive product was shown to the potential purchasers in conjunction with the offer to sell, the offer was enough to bar a patent under 35 U.S.C. 102(b)).

### III. SALE BY INVENTOR, ASSIGNEE OR OTHERS ASSOCIATED WITH THE INVENTOR IN THE COURSE OF BUSINESS

#### A. Sale Activity Need Not Be Public

Unlike questions of public use, there is no requirement that "on sale" activity be "public." "Public" as used in 35 U.S.C. 102(b) modifies "use" only. "Public" does not modify "sale." *Hobbs v. United States*, 451 F.2d 849, 171 USPQ 713, 720 (5th Cir. 1971).

#### B. Inventor's Consent to the Sale Is Not a Prerequisite To Finding an On Sale Bar

If the invention was placed on sale by a third party who obtained the invention from the inventor, a patent is barred even if the inventor did not consent to the sale or have knowledge that the invention was embodied in the sold article. *Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 41 USPQ 155 (1938); *In re Blaisdell*, 242 F.2d 779, 783, 113 USPQ 289, 292 (CCPA 1957); *CTS Corp. v. Electro Materials Corp. of America*, 469 F. Supp. 801, 819, 202 USPQ 22, 38 (S.D.N.Y. 1979).

#### C. Objective Evidence of \*>Sale or Offer< To Sell Is Needed

In determining if a sale or offer to sell >the claimed invention< has occurred, a key question to ask is whether, under the totality of the circumstances, the inventor \*\*>sold or offered< for sale \* a product that embodies the invention claimed in the application. Objective evidence such as a description of the inventive product in the contract of sale or in another communication with the purchaser controls over an uncommunicated intent by the seller to deliver the inventive product under the contract for sale. *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1567, 33 USPQ2d 1512, 1516 (Fed. Cir. 1995) (On sale bar found where initial negotiations and agreement containing contract for sale neither clearly specified nor precluded use of the inventive design>,< but an order confirmation

\*\*>prior to the critical date< did specify use of inventive design.). The purchaser need not have actual knowledge of the invention for it to be on sale. \*\*>The determination of whether “the< offered product is in fact the claimed invention may be established by any relevant evidence, such as memoranda, drawings, correspondence, and testimony of witnesses.” RCA Corp. v. Data Gen. Corp., 887 F.2d 1056, 1060, 12 USPQ2d 1449, 1452 (Fed. Cir. 1989). However, “what the purchaser reasonably believes the inventor to be offering is relevant to whether, on balance, the offer objectively may be said to be of the patented invention.” Envirotech Corp. v. Westech Eng’g, Inc., 904 F.2d 1571, 1576, 15 USPQ2d 1230, 1234 (Fed. Cir. 1990) (Where a proposal to supply a general contractor with a product did not mention a new design but, rather, referenced a prior art design, the uncommunicated intent of the supplier to supply the new design if awarded the contract did not constitute an “on sale” bar to a patent on the new design, even though the supplier’s bid reflected the lower cost of the new design.).

#### IV. SALES BY INDEPENDENT THIRD PARTIES

##### A. Sales or Offers for Sale by Independent Third Parties Will Bar a Patent

Sale or offer for sale of the invention by an independent third party more than 1 year before the filing date of applicant’s patent will bar applicant from obtaining a patent. “An exception to this rule exists where a patented method is kept secret and remains secret after a sale of the unpatented product of the method. Such a sale prior to the critical date is a bar if engaged in by the patentee or patent applicant, but not if engaged in by another.” In re Caveney, 761 F.2d 671, 675-76, 226 USPQ 1, 3-4 (Fed. Cir. 1985).

B. Nonprior Art Publications Can Be Used as Evidence of Sale Before the Critical Date  
Abstracts identifying a product’s vendor containing information useful to potential buyers such as whom to contact, price terms, documentation, warranties, training and maintenance along with the date of product release or installation before the inventor’s critical date may provide sufficient evidence of prior sale by a third party to support a rejection based on 35 U.S.C. 102(b) or 103. In re Epstein, 32 F.3d 1559, 31 USPQ2d 1817 (Fed. Cir. 1994) (Examiner’s rejection was based on nonprior art published abstracts which disclosed software products meeting the claims. The abstracts specified software release dates and dates of first installation which were more than 1 year before applicant’s filing date.).



#### 716.01 Generally Applicable Criteria

The following criteria are applicable to all evidence traversing rejections submitted by applicants, including affidavits or declarations submitted under 37 CFR 1.132:

(A) Timeliness. Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. In re Rothermel, 276 F.2d 393, 125 USPQ 328 (CCPA 1960). Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted:

- (1) prior to a final rejection,
- (2) before appeal in an application not having a final rejection, or
- (3) after final rejection and submitted
  - (i) with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection, or
  - (ii) with a satisfactory showing under 37 CFR 1.116(b) or 37 CFR 1.195, or
  - (iii) under 37 CFR 1.129(a).

(B) Consideration of evidence. Evidence traversing rejections must be considered by the examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action. The extent of the commentary depends on the action taken by the examiner. Where an examiner holds that the evidence is sufficient to overcome the prima facie case, the comments should be consistent with the guidelines for statements of reasons for allowance. See MPEP § 1302.14. Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as "the declaration lacks technical validity" or "the evidence is not commensurate with the scope of the claims" without an explanation supporting such findings are insufficient.

**TO BE OF PROBATIVE VALUE, ANY OBJECTIVE EVIDENCE SHOULD  
BE SUPPORTED BY ACTUAL PROOF**

Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date

of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument.").

See

also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

**ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE**

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

See MPEP § 2145 generally for case law pertinent to the consideration of applicant's rebuttal arguments